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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of: U.S. Patent No. 5,750,338	)	
Mark L. Collins et al.	)	Group Art Unit: 1655
Reissue Serial No.: 09/533,906	)	Examiner: D. Johannsen
Reissue Application Filed: March 8, 2000	)	
For: TARGET AND BACKGROUND CAPTURE METHODS WITH AMPLIFICATION FOR AFFINITY ASSAYS	)	

REISSUE LITIGATION BOX
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

SUPPLEMENTAL AMENDMENT

Further to the Amendment submitted on March 8, 2002, the draft proposed Examiner's Amendment forwarded by facsimile on March 28, 2002, the Interview of April 2, 2002, and the Interview Summary forwarded by facsimile on April 3, 2002 (but not yet mailed), the Patent Owner requests that the application be amended as follows:

IN THE CLAIMS

In the originally issued claims 1-40, please cancel claims 20-26 without prejudice. Please amend original claims 1, 4-7, 10-14, 16-19, 27-30, 32, 34-36, and 38-39 as follows:

1. (Twice Amended) A method for amplifying a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

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(b) substantially separating the support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide; and

(c) amplifying *in vitro* the separated target polynucleotide of (b).

4. (Amended) The method of claim 1 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

5. (Amended) The method of claim 4 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase [or Qβ replicase].

6. (Amended) The method of claim 4 wherein the separated target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.

7. (Twice Amended) A method for detecting a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

(b) substantially separating the first support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide;

(c) amplifying *in vitro* the separated target polynucleotide of (b), thereby producing an amplified target polynucleotide; and

(d) detecting the presence of the amplified target polynucleotide of (c) as indicative of the presence of the target polynucleotide in said sample.

10. (Amended) The method of claim 7 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

11. (Amended) The method of claim 10 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase [or Qβ replicase].

12. (Amended) The method of claim 11 wherein the separated target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.

13. (Amended) The method of claim 7 wherein the amplified target polynucleotide is

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contacted with a label, and the presence of the target polynucleotide in the sample is indicated by detection of said label.

14. (Amended) The method of claim 7 wherein the amplified target polynucleotide is contacted with a labeled probe, and the presence of the target polynucleotide in the sample is indicated by detection of said labeled probe.

16. (Amended) The method of claim 15 wherein the [amplified target polynucleotide is contacted with] second support includes a labeled probe, and the presence of the target polynucleotide in the sample is indicated by detection of said labeled probe.

17. (Amended) The method of claim 16 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

18. (Amended) The method of claim 17 wherein the separated target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.

19. (Three-times Amended) A method for detecting a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

(b) substantially separating the first support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide;

(c) amplifying *in vitro* the [sample] separated target polynucleotide of (b) with a DNA polymerase, thereby producing an amplified target polynucleotide;

(d) contacting the amplified target polynucleotide of (c) with a second support which binds to the amplified target polynucleotide and also with a labeled probe which binds to the amplified target polynucleotide; and

(e) detecting the presence of [the amplified target polynucleotide] the labeled probe as indicated of the presence of the target polynucleotide in said sample.

27. (Twice Amended) A method for amplifying a target polynucleotide contained in a sample medium comprising the steps of:

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(a) contacting the sample medium with a reagent comprising a first nucleic acid probe which binds to the target polynucleotide to form a probe-target complex;

(b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;

(c) substantially separating the support and bound probe-target complex from the sample medium;

(d) contacting the support and bound probe-target complex with a second medium;

(e) releasing the probe-target complex into the second medium;

(f) substantially separating the support from the second medium; and

(g) amplifying *in vitro* the target polynucleotide in the probe-target complex present in the second medium.

28. (Twice Amended) A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a reagent comprising a first nucleic acid probe which binds to the target polynucleotide to form a probe-target complex;

(b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;

(c) substantially separating the support and bound probe-target complex from the sample medium;

(d) contacting the support and bound probe-target complex with a second medium;

(e) releasing the probe-target complex into the second medium;

(f) substantially separating the support from the second medium;

(g) amplifying *in vitro* the target polynucleotide in the probe-target complex present in the second medium; and

(h) detecting the presence of the target polynucleotide in the second medium as indicative of the presence of the target polynucleotide in said sample.

29. (Amended) The method of detecting a target polynucleotide of claim 28 wherein [the

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target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

30. (Amended) The method for detecting a target polynucleotide of claim 29 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase[, or Qβ replicase].

32. (Amended) The method for amplifying a target polynucleotide of claim 27 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

34. (Twice Amended) A method for amplifying a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a support and a probe which binds to the target polynucleotide and the support;

(b) substantially separating the support and bound probe and target polynucleotide from the sample medium;

(c) contacting the support and bound probe and target polynucleotide with a second medium;

(d) releasing the target polynucleotide of (c) into the second medium;

(e) substantially separating the support and bound probe from the second medium; and

(f) amplifying *in vitro* the target polynucleotide present in the second medium.

35. (Twice Amended) The method for amplifying a target polynucleotide of claim 34 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

36. (Amended) The method for amplifying a target polynucleotide of claim 35 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase [or Qβ replicase].

38. (Twice Amended) A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a support and probe which binds to the target polynucleotide and the support;

(b) substantially separating the support and bound probe and target polynucleotide from the

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sample medium;

(c) contacting the support and bound probe and target polynucleotide with a second medium;

(d) releasing the target polynucleotide of (c) into the second medium;

(e) substantially separating the support and bound probe [form] from the second medium;

(f) amplifying *in vitro* the target polynucleotide present in the second medium, thereby producing an amplified target polynucleotide; and

(g) detecting the presence of the amplified target polynucleotide in the second medium as indicative of the presence of the target polynucleotide in said sample.

39. (Amended) The method for detecting a target polynucleotide of claim 38 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

Of the claims 41-59 introduced in the Preliminary Amendment of March 8, 2000, please cancel claims 41, 47, and 53-59 without prejudice (if they have not yet been canceled). Please amend claims 42-46 and 48-52 as follows: (the attached Appendix I identifies the changes from the claims as introduced):

42. The amplification method of claim 1 wherein said amplifying *in vitro* is linear or exponential.

43. The amplification method of claim 41 wherein said amplifying *in vitro* is exponential.

44. The amplification method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with at least one oligonucleotide primer.

45. The amplification method of claim 43 wherein said amplifying *in vitro* is linear or exponential.

46. The amplification method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase.

48. The detection method of claim 7 wherein said amplifying *in vitro* is linear or exponential.

49. The detection method of claim 46 wherein said amplifying *in vitro* is exponential.

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50. The detection method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with at least one oligonucleotide primer.

51. The detection method of claim 50 wherein said amplifying *in vitro* is linear or exponential.

52. The detection method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase.

Please cancel claims 60-63 added by the Preliminary Amendment of July 16, 2001 (if they are not already canceled).

Of the claims 64-82 added in the Amendment of March 8, 2002, please cancel claims 68, 69, and 76-82 without prejudice. Please amend claims 64-67 and 71-72 as follows (the attached Appendix I identifies the changes from the claims as introduced):

64. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide non-specifically.

65. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide specifically.

66. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide non-specifically.

67. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide specifically.

71. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide non-specifically.

72. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide specifically.

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Please add new claims 83-86 as follows:

83. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with specially tailored primers.

84. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with specially tailored primers.

85. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with specially tailored primers.

86. The method of claim 85 wherein the sample is a clinical sample.

REMARKS

The Patent Owner and its representatives wish to express their appreciation to each of the PTO representatives that has participated in the examination of this application. Specifically, the Patent Owner thanks Supervisory Primary Examiner Gary Jones, Special Programs Examiner Julie Burke, Primary Examiner Carla Myers, Primary Examiner Lisa Arthur, and particularly, Examiner Dianna Johannsen.

The amendments presented here reflect the draft proposed amendment of March 28, 2002, as discussed and modified during the interview of April 2, 2002, and as reflected in the Interview Summary forwarded by facsimile on April 3, 2002. After these amendments, claims 1-19, 27-40, 42-46, 48-52, 64-67, 70-75, and 83-86 will be pending. As discussed with the Examiner on Friday, April 11, 2002, the prior request to cancel claim 44 in the March 8th Amendment has not yet been entered so that claim is currently pending and has been amended in this Supplemental Amendment. To assist the Office, a clean copy of these pending claims is attached in Appendix II.

As noted during the Interview, the submission of additional claim amendments necessitates the filing of a supplemental oath/declaration to satisfy the requirements of 35 U.S.C. 251. Accordingly, the Patent Owner is submitting herewith a second supplemental reissue declaration by its representative Norval Galloway that states that:

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All errors which are being corrected in the present reissue application up to the time of the filing of this second supplemental oath/declaration, and which are not covered by a prior oath/declaration submitted in this application, arose without any deceptive intent on the part of the applicant.

For the foregoing reasons, the Patent Owner respectfully submits that the claims are in condition for allowance and earnestly requests prompt notification to this effect.

If there are any fees due in connection with the filing of this Supplemental Amendment not already accounted for, please charge the fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

By: Jean Burke Fordis
Jean Burke Fordis
Reg. No. 32,984

Dated: April 15, 2002
30209

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Appendix I showing amendments to claims added during prosecution

42. The amplification method of claim [41] 1 wherein said amplifying *in vitro* [the amplification] is linear or exponential.

43. The amplification method of claim 42 wherein said amplifying *in vitro* [the amplification] is exponential.

44. The amplification method of claim [41] 1 wherein said amplifying *in vitro* comprises amplifying said [the] separated target polynucleotide [is amplified] with [a polymerase and] at least one oligonucleotide primer.

45. The amplification method of claim 44 wherein [the amplification] said amplifying *in vitro* is linear or exponential.

46. The amplification method of claim [41] 1 wherein [the target polynucleotide is amplified with more than one polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase.

48. The detection method of claim [47] 7 wherein [the amplification] said amplifying *in vitro* is linear or exponential.

49. The detection method of claim 48 wherein [the amplification] said amplifying *in vitro* is exponential.

50. The detection method of claim [47] 7 wherein said amplifying *in* vitro comprises amplifying said [the] separated target polynucleotide [is amplified] with [a polymerase and] at least one oligonucleotide primer.

51. The detection method of claim 50 wherein [the amplification] said amplifying *in vitro* is linear or exponential.

52. The detection method of claim [47] 7 wherein [the target polynucleotide is amplified with more than one polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase.

64. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said [the] separated target polynucleotide [is amplified] non-specifically [with random primers].

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65. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said [the] separated target polynucleotide [is amplified] specifically [with specially tailored primers].

66. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said [the] separated target polynucleotide [is amplified] non-specifically [with random primers].

67. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said [the] separated target polynucleotide [is amplified] specifically [with specially tailored primers].

71. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said [the] separated target polynucleotide [is amplified] non-specifically [with random primers].

72. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said [the] separated target polynucleotide [is amplified] specifically [with specially tailored primers].

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Appendix II with a clean copy of

pending claims 1-19, 27-40, 42-46, 48-52, 64-67, 70-75, and 83-86

1. A method for amplifying a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

(b) substantially separating the support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide; and

(c) amplifying *in vitro* the separated target polynucleotide of (b).

2. The method of claim 1 wherein the first support is retrievable.

3. The method of claim 1 wherein the first support includes a probe which binds with the target polynucleotide.

4. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

5. The method of claim 4 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase.

6. The method of claim 4 wherein the separated target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.

7. A method for detecting a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

(b) substantially separating the first support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide;

(c) amplifying *in vitro* the separated target polynucleotide of (b), thereby producing an amplified target polynucleotide; and

(d) detecting the presence of the amplified target polynucleotide of (c) as indicative of the presence of the target polynucleotide in said sample.

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8. The method of claim 7 wherein the first support is retrievable.

9. The method of claim 8 wherein the first support includes a probe which binds with the target polynucleotide.

10. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

11. The method of claim 10 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase.

12. The method of claim 11 wherein the separated target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.

13. The method of claim 7 wherein the amplified target polynucleotide is contacted with a label, and the presence of the target polynucleotide in the sample is indicated by detection of said label.

14. The method of claim 7 wherein the amplified target polynucleotide is contacted with a labeled probe, and the presence of the target polynucleotide in the sample is indicated by detection of said labeled probe.

15. The method of claim 7 wherein the amplified target polynucleotide is contacted with a second support which binds to the amplified target polynucleotide.

16. The method of claim 15 wherein the second support includes a labeled probe, and the presence of the target polynucleotide in the sample is indicated by detection of said labeled probe.

17. The method of claim 16 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

18. The method of claim 17 wherein the separated target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.

19. A method for detecting a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

(b) substantially separating the first support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide;

(c) amplifying *in vitro* the separated target polynucleotide of (b) with a DNA polymerase, thereby producing an amplified target polynucleotide;

(d) contacting the amplified target polynucleotide of (c) with a second support which binds to the amplified target polynucleotide and also with a labeled probe which binds to the amplified target polynucleotide; and

(e) detecting the presence of the labeled probe as indicative of the presence of the target polynucleotide in said sample.

[claims 20-26 canceled]

27. A method for amplifying a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a reagent comprising a first nucleic acid probe which binds to the target polynucleotide to form a probe-target complex;

(b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;

(c) substantially separating the support and bound probe-target complex from the sample medium;

(d) contacting the support and bound probe-target complex with a second medium;

(e) releasing the probe-target complex into the second medium;

(f) substantially separating the support from the second medium; and

(g) amplifying *in vitro* the target polynucleotide in the probe-target complex present in the second medium.

28. A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a reagent comprising a first nucleic acid probe which binds to the target polynucleotide to form a probe-target complex;

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(b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;

(c) substantially separating the support and bound probe-target complex from the sample medium;

(d) contacting the support and bound probe-target complex with a second medium;

(e) releasing the probe-target complex into the second medium;

(f) substantially separating the support from the second medium;

(g) amplifying *in vitro* the target polynucleotide in the probe-target complex present in the second medium; and

(h) detecting the presence of the target polynucleotide in the second medium as indicative of the presence of the target polynucleotide in said sample.

29. The method of detecting a target polynucleotide of claim 28 wherein said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

30. The method for detecting a target polynucleotide of claim 29 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase.

31. The method for detecting a target polynucleotide of claim 30 wherein the polymerase is a DNA polymerase.

32. The method for amplifying a target polynucleotide of claim 27 wherein said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

33. The method for amplifying a target polynucleotide of claim 32 wherein the polymerase is a DNA polymerase.

34. A method for amplifying a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a support and a probe which binds to the target polynucleotide and the support;

(b) substantially separating the support and bound probe and target polynucleotide from the sample medium;

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(c) contacting the support and bound probe and target polynucleotide with a second medium;

(d) releasing the target polynucleotide of (c) into the second medium;

(e) substantially separating the support and bound probe from the second medium; and

(f) amplifying *in vitro* the target polynucleotide present in the second medium.

35. The method for amplifying a target polynucleotide of claim 34 wherein said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

36. The method for amplifying a target polynucleotide of claim 35 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase.

37. The method for amplifying a target polynucleotide of claim 36 wherein the polymerase is a DNA polymerase.

38. A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a support and probe which binds to the target polynucleotide and the support;

(b) substantially separating the support and bound probe and target polynucleotide from the sample medium;

(c) contacting the support and bound probe and target polynucleotide with a second medium;

(d) releasing the target polynucleotide of (c) into the second medium;

(e) substantially separating the support and bound probe from the second medium;

(f) amplifying *in vitro* the target polynucleotide present in the second medium, thereby producing an amplified target polynucleotide; and

(g) detecting the presence of the amplified target polynucleotide in the second medium as indicative of the presence of the target polynucleotide in said sample.

39. The method for detecting a target polynucleotide of claim 38 wherein said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

40. The method for detecting a target polynucleotide of claim 39 wherein the polymerase is a DNA polymerase.

[claim 41 canceled]

42. The amplification method of claim 1 wherein said amplifying *in vitro* is linear or exponential.

43. The amplification method of claim 42 wherein said amplifying *in vitro* is exponential.

44. The amplification method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with at least one oligonucleotide primer.

45. The amplification method of claim 44 wherein said amplifying *in vitro* is linear or exponential.

46. The amplification method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase.

[claim 47 canceled]

48. The detection method of claim 7 wherein said amplifying *in vitro* is linear or exponential.

49. The detection method of claim 48 wherein said amplifying *in vitro* is exponential.

50. The detection method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with at least one oligonucleotide primer.

51. The detection method of claim 50 wherein said amplifying *in vitro* is linear or exponential.

52. The detection method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase.

[claims 53-63 canceled]

64. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide non-specifically.

65. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide specifically.

66. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide non-specifically.

67. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide specifically.

[claims 68-69 canceled]

70. The method of claim 9 wherein the probe first binds with the target polynucleotide by hybridizing to a specific sequence in the target polynucleotide, and then binds to the first support.

71. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide non-specifically.

72. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide specifically.

73. The method of claim 72 wherein the sample is a clinical sample.

74. The method of claim 73 wherein the probe comprises a nucleotide sequence specific to a complementary nucleotide sequence in the target polynucleotide and a homopolymeric tail sequence.

75. The method of claim 74 wherein the support comprises a homopolymeric tail complementary to the homopolymeric tail of the probe.

[claims 76-82 canceled]

83. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with specially tailored primers.

84. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with specially tailored primers.

85. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with specially tailored primers.

86. The method of claim 85 wherein the sample is a clinical sample.

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